



Bureau of State Laboratory Services
Office of Laboratory Licensure, Certification & Training

1740 W. Adams, Room 203
Phoenix, Arizona 85007
(602) 364-0720
(602) 364-0758 FAX
1-800-952-0374

JANE DEE HULL, GOVERNOR
CATHERINE R. EDEN, DIRECTOR

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FROM: Wesley B. Press, Bureau Chief

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Technical Support Hot-Line 1-800-952-0374

E-mail: pachary@hs.state.az.us

<http://www.hs.state.az.us/lab/license/tech/infoup.htm>

JANE DEE HULL, GOVERNOR

CATHERINE R. EDEN, DIRECTOR

Information Update

December 17, 2002

Update #78

1. The Technical Resources and Training Program is tentatively planning to have two workshops during the first week of March 2003, "Detecting and Correcting Inappropriate Laboratory Practices" and "Manual Integration Training Course". There is a limit on the number of participants for both the classes, 40 for the first workshop and 30 for the second one. We are planning to have multiple sessions of each workshop to accommodate more participants. Mr. Jack Farrell of Analytical Excellence, Inc. will present the workshops. Several technical associates versed in laboratory practices and analytical software will accompany Mr. Farrell.

Detecting and Correcting Inappropriate Laboratory Practices

(Registration fees between \$125.00-\$150.00)

This one-day training program has been presented all over the U.S. at industry meetings, government agency conferences, for government laboratories and private companies. It was heavily attended by laboratory analysts, QA officers, managers, regulators and federal enforcement officers. The program is both practical and timely as well as interactive and entertaining.

Discussion topics include potential causes of scientific misconduct, examples of improper practices, and specific practices designed for early detection, resolving ethical dilemma, differentiating between proper and wrongful practices and the role of an effective quality system in preventing laboratory wrongdoing. Auditors, lab managers, senior chemists, owners and QA managers will benefit from this sharing of examples and successful detection systems. Ample time will be provided for questions and discussion of real life examples. The format contains lecture, large group exercises and small group interactive exercises and demonstrations.

A rough agenda for the training program includes:

- I. Introduction.....5 min.

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| II. Review of Agenda and Logistics..... | 5 min. |
| III. Purpose and Objectives | 10 min. |
| IV. The Rationale and Initiatives for Implementing Ethical Practices and the Ramifications of Ethical Lapses in Environmental Labs | 30 min. |
| V. The Role of a Functioning Quality System in Preventing Inappropriate Practices Within the Laboratories..... | 45 min. |
| Short Break..... | 15 min. |
| VI. Establishing Values for Your Organization and Examples Statements of Value | 30 min. |
| VII. Small Group Exercise on Developing Shared Values for Your Organization + Lunch | 60 min. |
| VIII. Causes of Improper Practices - Root Cause Analysis..... | 60 min. |
| IX. Examples of Improper Practices Found..... | 60 min. |
| X. Small Group Exercise - Manual Integrations; Progress to Disaster (Short Break Included) | 45 min. |
| XI. Establishing Ethical Practices and Management's Role in Prevention | 60 min. |
| XII. Small Group Exercise - The Method Blank Dilemma..... | 30 min. |
| XIII. Review, Summary & Discussion..... | 30 min. |

Manual Integration Training Course - One day course

(Registration fees between \$225.00-\$250.00)

The complexity of environmental chromatographic, organic and inorganic, has raised a number of issues. One that has caused significant difficulty centers on the proper set up of instrument integration parameters and the use of manual integration techniques. In an open letter to environmental laboratories dated September 5, 2002, the EPA-OIG expressed a strong concern regarding the misuse of manual integration techniques to bypass quality control requirements. It has, therefore, become increasingly important for analysts and data reviewers to be well versed in the techniques of quantification and integration of complex chromatographic analyses. Clearly, there is complexity due to a variety of matrix effects, interferences, changing instrument conditions, a multitude of closely eluting target analytes and imperfections in chromatographic methods and data system algorithms. These complexities require specific training and experience in both setting instrument integration and quantification

parameters, and in performing scientifically sound manual integrations.

This training course discusses the basics of calibration, peak detection, instrument integration and peak detection algorithm set up and usage. This proposed training course will address the issues of refining software parameters to try and minimize the need for manual integrations, as well as defining proper methods for performing manual integrations when they are necessary. The majority of the course will be presented using graphical tools including actual chromatograms and methods used for demonstrations. Students are encouraged to provide examples of difficult integration problems for discussion and resolution. The format of the program contains limited lecture, large group and small group exercises along with opportunities for live demonstrations using applicable and available data system software.

A rough course agenda is below:

- I. Introduction
 - a. Why is this an important issue?
 - b. What is peak detection and integration?
 - c. What are the tools available and the differences in software systems?
- II. Automated Peak Detection - How Does It Work?
 - a. Identification requirements and criteria;
 - b. Threshold and area reject;
 - c. Slope and sensitivity;
 - d. Peak width;
 - e. Proper documentation.
- III. Enhancing Automated Peak Detection Parameters - Examples
 - a. Autointegration using HP Chemstation integrator (GC only);
 - b. Refining HP Chemstation integrator events;
 - c. Refining HP RTE integrator events.
- IV. Manual Integration Basics
 - a. What is a manual integration?
 - b. How manual integrations are performed?
 1. 2-D Data (GC and LC);
 2. 3-D Data (GC/MS).
 - c. Why manual integrations are necessary?
 1. Co-elutions;
 2. Complex sample matrices;
 3. Baseline fluctuations.
- V. Proper Manual Integration
 - a. Single peak;
 - b. Co-elutions;
 - c. Hydrocarbon envelopes;
 - d. Single components in complex matrices;
 - e. Proper Documentation.
- VI. Proper vs. Improper Manual Integration
 - a. Defining an improper manual integration;
 - b. Peak trimming;
 - c. Peak enhancement;

- d. Improper peak identification.

VII. Conclusion and Questions

Please respond to us by fax [(602) 364-0758] before January 02, 2003 if you are interested in attending these workshops, so that we can make appropriate plans.

2. If you have any questions regarding the Information Updates, or if you have any technical questions that need clarification, please call or send e-mail to Prabha Acharya, Program Manager, Technical Resources and Training, at the Laboratory Licensure numbers/address. Copies of the Information Updates can now be found at our internet address:
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